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08/797,770	02/07/1997	ANDREW D. BAROFSKY	4430-18	1692

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EXAMINER

PREBILIC, PAUL B

ART UNIT PAPER NUMBER

3738

DATE MAILED: 10/21/2003

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Paper No. 47

Application Number: 08/797,770  
Filing Date: February 07, 1997  
Appellant(s): BAROFSKY ET AL.

**MAILED**  
**OCT 22 2003**  
**GROUP 3700**

\_\_\_\_\_  
Jerome Marger  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed June 30, 2003.

**(1) *Real Party in Interest***

A statement identifying the real party in interest is contained in the brief.

**(2) *Related Appeals and Interferences***

A statement identifying the related appeals and interferences, which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

**(3) *Status of Claims***

The statement of the status of the claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

This appeal involves claims 1-13, 15-24, 36-39, 41-55, 74, 76-100 and 103-104.

Claims 101 and 102 are allowed.

Claims 14, 25-35, 40, 56-73 and 75 have been canceled.

**(4) *Status of Amendments After Final***

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) *Summary of Invention***

The summary of invention contained in the brief is correct.

**(6) *Issues***

The Appellants' statement of the issues in the brief is substantially correct. The changes are as follows:

The First Issue has been removed because the Examiner has withdrawn the rejection as of the date of this Examiner's Answer.

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The Second Issue is not correct because claims 101 and 102 are not rejected. Therefore, claims 1-13, 15-24, 36-39, 41-55, 74, 76-100, and 103-104 are considered anticipated by Gregory et al (WO 96/14807).

The Third Issue is not correct because claims 101 and 102 are not rejected. Therefore, claims 1-13, 15-24, 36-39, 41-55, 74, 76-100, and 103-104 are considered obvious over Gregory et al (WO 96/14807) in view of Labroo (US 5,428,014).

The Fourth Issue is not correct because the Examiner inadvertently listed claim 48 therewith even though it is dependent upon claim 100. Therefore, claim 47 is considered anticipated by Appellants' admission with respect to the Bedell-Hogan et al article.

The Fifth Issue has been removed because the Examiner has withdrawn the rejection as of the date of this Examiner's Answer.

**(7) Grouping of Claims**

The Appellants have stated that the claims stand or fall together with the particular rejections they are associated.

**(8) Claims Appealed**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(9) Prior Art of Record**

WO 96/14807	Gregory et al	05-1996
US 5,428,014	Labroo et al	06-1995

**(10) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-13, 15-24, 36-39, 41-55, 74, 76-100, and 103-104 are rejected under 35 U.S.C. 102(a) as anticipated by Gregory et al (WO 96/14807) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gregory et al (WO 96/14807) in view of Labroo et al (US 5,428,014). Gregory et al is viewed as anticipating the present claims because crosslinked or polymerized tropoelastin is elastin even though it is not called such in the disclosure because the tropoelastin is uncrosslinked and unpolymerized precursor to elastin (i.e. this is definition of tropoelastin in the present specification); see the entire disclosure of Gregory et al, especially Figure 1, page 1, lines 12-23 and page 8, line 21 to page 9, line 9. In other words, tropoelastin monomer is merely a precursor to elastin such that when tropoelastin is formed into a biomaterial by crosslinking or polymerization, it becomes elastin. Therefore, the term tropoelastin biomaterial, as defined in the present specification as crosslinked or polymerized tropoelastin, is actually elastin or elastin-based material. For these reasons, the claims are anticipated by Gregory et al (WO).

Alternatively, one may not consider the claims anticipated by Gregory et al because tropoelastin is not explicitly stated therein. However, the Examiner posits that it would have been obvious to use tropoelastin as the elastin-like material of Gregory et al because it is so similar to elastin in tissue binding properties that it is considered interchangeable therewith; see Labroo et al on Col. 9, lines 1-26. Furthermore, it is prima facie obvious to use tropoelastin in the Gregory et al invention because it is an elastin-based material as required by Gregory et al.

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Claim 47 is rejected under 35 U.S.C. 102(b) as being anticipated by Applicant's Admission wherein the claimed process of tropoelastin polymerization reads on the natural process of elastin formation in vertebrates according to Bedell-Hogan, et al in the Journal of Biological Chemistry; see page 1, lines 12-23 of the present specification.

**(11) Response to Argument**

**First Issue**

Withdrawn as of the date of this Examiner's Answer.

**Second Issue**

Appellants argue that the 37 CFR 1.131 declarations establish completion of the invention prior to the effective date. However, the Examiner asserts that the declarations are inadequate because they fail to show either conception or reduction to practice.

With regard to the Dr. Maslen declaration, the Examiner asserts that Dr. Maslen's declaration does not meet one of the four requirements for filing a 37 CFR 1.131 declaration; see MPEP 715.04 which is incorporated herein by reference.

Furthermore, although completion of the invention is alleged by Dr. Maslen prior to the critical date (see paragraph 1), the evidence provided fails to establish that the claimed method was performed at any time. Rather, it states and shows some evidence that tropoelastin was worked with from September 1995 until February 7, 1997 (the filing date of the present invention; see paragraphs 3 to 7).

With regard to the Dr. Gregory declaration, the Examiner determined that Dr. Gregory appears to meet one of the four requirement for filing a 37 CFR 1.131

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declaration because he is listed as a real party in interest (see Section II of the present Appeal Brief); see paragraph "(D)" in MPEP 715.04. However, since it was not established that it was not possible to have all the inventors execute the declaration, the Dr. Gregory declaration may be insufficient for this reason. Even if the declaration is sufficient with respect to the four requirements, the Examiner asserts that the declaration fails to establish that the claimed invention was completed prior to the critical date May 23, 1996. Rather, on the critical date, broad statements were made of possible uses of tropoelastin; see tab# 1. This evidence is not prior to the critical date, and it fails to provide evidence that the claimed methods were known and completed prior to the critical date.

Even though the invention was alleged to be complete prior to the critical date, Appellants attempt to show that diligence was present from the critical date to the filing date of the present application. However, there is no clear evidence of conception for the claimed invention. Furthermore, the evidence only shows that tropoelastin was being worked with between May 1996 and February 1997. The evidence is not commensurate with the scope of the claims; see MPEP 715.02.

With regard to the Appellants' arguments that diligence occurred between May 23, 1996 and February 7, 1997, the Examiner notes that diligence does not need to be shown when an invention is complete. Even if one thought that diligence was necessary to show, and that conception took place prior to the critical date, the Examiner asserts that the evidence of diligence is insufficient; see MPEP 715.07, which is incorporated herein by reference.

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It is noted that the Appellant has not argued the material validity of the Section 102(a) Gregory et al rejection. For this reason, it is asserted the rejection remains a valid one because Appellants' have not argued its validity with respect to the substance of the rejection. Rather, Appellants' have argued that the Gregory patent is inappropriate via the 37 CFR 1.131 declaration. Since the 37 CRR 1.131 declaration is insufficient, it follows that the rejection should be maintained.

### **Third Issue**

The only new arguments set forth as compared to the related Section 102 Gregory rejection (Second Issue) above is that Labroo is to a copolymer combination, and that the Examiner has used hindsight reasoning to combine Labroo with Gregory. However, the Examiner asserts that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Furthermore, in response to Appellants' argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Appellants' disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Since the reconstruction is based in Labroo's teaching only, the Examiner has not used improper hindsight reasoning.



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**Fourth Issue**

Contrary to the Appellant's statement pertaining to this issue, the rejection is not based entirely on Bedell-Hogan et al. Rather, it is based upon the Appellant's admission or description of the Bedell-Hogan et al article; see page 1, lines 12-23 of the Appellants' specification. Upon reading this admission, the Examiner concluded that although the exact method is not stated in Appellants' description of Bedell-Hogan et al, the claimed method is inherent to the articles description of the naturally occurring process of tropoelastin crosslinking to form elastin. For this reason, the claim language is considered to be fully met under Section 102(b).

**Fifth Issue**

The rejection utilizing Labroo under Section 102(b) has been withdrawn, and thus, the arguments pertaining thereto are moot.

For the above reasons, it is believed that the rejections should be sustained.


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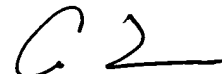
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Respectfully submitted,

pbp  
October 16, 2003

  
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